Old Problems + New Technology = BIG IDEAS!

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SPINAL CORD STIUMULATORS: The Old and The New

June 7, 2018 Jeffrey E. Hazlewood, MD

Traditional Units

- Deliver electrical impulses via spinal epidural electrode arrays (leads) at vertebral levels associated with perceived pain
- Traditional units are capable of delivering pulse frequencies in the range of 2 to 1,200 Hz, with typical application of approximately 40 to 60 Hz
- The objective of these units: produce paresthesias that overlap the pain distribution, with the intent of masking pain perception

Traditional Units

- Success depends on adequacy and durability of paresthesia coverage as well as patient tolerance of the induced sensations
- Axial low back pain is more difficult to treat and limits application mostly to patients with predominantly leg pain

• Involves application of short-duration (30 microseconds), high-frequency (10 kHz), low-amplitude (1 to 5 mA) pulses to the spinal epidural space in such a manner as not to produce paresthesia

- Medtronic
 - "Intellis"
 - Gives patients option to switch between high-dose and low-dose therapy
 - 40% smaller and recharges more quickly
- Nevro
 - Senza II System
- Abbott
 - "BurstDR"
- Boston Scientific
 - "Spectra WaveWriter"

- SUNBURST study—Dr Peter Staats
 - More than 50% of patients with chronic pain decreased their chronic pain after one year of therapy using burst spinal cord stimulation
 - Used the BurstDR system from Abbott
 - Uses five small 1,000-microsecond pulses of electricity with a passive recharge in between bursts
 - The bursts are delivered at 40 Hz

- SUNBURST study:
 - Of the 100 study patients with permanent implantations, 69 were taking opioids at baseline:
 - 80% preferred burst over low-frequency, tonic units
 - 51% decreased opioid dependence at one year
 - 26% completely weaned off opioids
 - Dr Staats' research was partially funded by Abbott though

- The SENZA-RCT Randomized Controlled Trial
 - Anesthesiology, V 123, No. 4, October 2015—Kapural, et al
 - Most patients were "Failed Back Syndrome"
 - 56% had predominantly back pain
 - Used the HF10 therapy (10 kHz), Nevro Senza System
 - 171 patients
 - The first scientifically rigorous, randomized, controlled trial demonstrating the superiority of HF10 therapy over traditional SCS in the long-term treatment of both back and leg pain

- The SENZA-RCT Randomized Controlled Trial
 - Results:
 - At 3 months, 85% were responders for back pain (vs 44% traditional)
 - At 3 months, 83% were responders for leg pain (vs 56% traditional)
 - The superiority of HF10 therapy over traditional SCS for leg and back pain was sustained through 12 months
 - Outcome assessment was VAS for back and leg pain, ODI, Global Assessment of Functioning

- The SENZA-RCT Randomized Controlled Trial
 - Results:
 - The emphasis of the study was on pain relief and not on reduction in pain medications, however:
 - 36% decreased or eliminated opioid analgesic usage at 12 months (26% traditional)
 - Average MEDD decreased from 112 mg to 87 mg (vs 125 to 118 traditional)
 - Patient satisfaction:
 - HF10: 55%
 - Traditional: 32%
 - Safety:
 - Incidence of SAE's: 4-7%
 - Lower lead migration rates: 5%

The Other Side:

WorkCompCentral Article

- Elaine Goodman, 2/26/18, quoting Dr. Steven Moskowitz, medical director of Paradigm Outcomes:
 - Must look in W/C at improved function and health, not just satisfaction and change in pain rating
 - Need return to work and decreased need for health care utilization (decreased meds, doctors visits, invasive procedures)
 - Not a covered benefit for Washington state health care agencies (including W/C)—2013
 - ACOEM—for most part don't recommend SCS
 - ODG—does recommend for selected situations if failed other options

WorkCompCentral Article

- Elaine Goodman, 2/26/18, quoting Dr. Steven Moskowitz, medical director of Paradigm Outcomes:
 - Oregon analysis (looked at claims 2010-2017):
 - 1/75 returned to regular work at one year post-op surgery for LBP
 - Of 71% using opioids, after SCS one year after surgery: 55% using opioids
 - 46% SCS implantation resulted in revisions to the equipment just over one year later
 - Significant impact in reduction of pain and decrease in the utilization of pain medications is NOT occurring

Other Articles:

- *Pain* 2010 Jan;148:
 - SCS has high removal rates and can be associated with complications after implant (infection, malfunction, more pain, bleeding)
 - No evidence for greater effectiveness of SCS vs alternative treatments in W/C patients after 6 months

Other Articles:

- Pain Medicine, Vol 17, Issue 2, February 2016:
 - Complication rates vary from 30-40% (most common is lead migration)
 - Also see infection and pain over the implant
- Psychiatric disorders can manifest after implantation:
 - Anesth Analg. 2003 Jan;96(1)—Conversion disorder
 - Psychosomatics. 1999 Jan-Feb; 40(1)—Schizophreniform disorder
 - Anesth. Analg. 2006 Nov;103(5)—Panic attacks

Landmark Study

- *PAIN* 148(2010), Tuner et al
 - SCS for failed back surgery syndrome: Outcomes in a W/C setting
 - Prospective, population-based controlled cohort study
 - 51 patient study

Landmark Study

- *PAIN* 148(2010), Tuner et al
 - Results:
 - <10% achieved success at any follow-up in terms of less daily opioid usage, improvement in leg pain, or improvement in function
 - At 6 months, there was some improvement in leg pain and function, but with HIGHER rates of daily opioid usage—improvement disappeared at 12 months
 - No difference from patients who received other pain clinic treatment at any followup
 - 19% had the SCS removed within 18 months

Landmark Study

- PAIN 148(2010), Tuner et al
 - IN SUMMARY:
 - No evidence was found for greater effectiveness of SCS vs alternative treatments in W/C patients after 6 months

Other Concerns:

- Lack of compatibility in MRI scanners (Spine 2015 40(9))
- Not cost-effective per some studies (Spine 2011 36(24))
- BARTH:
 - "The harmful nature of SCS (and pain pumps) is illustrated by the fact that they force a life-sentence on the claimant of permanently being in a patient-role (and they do this in the absence of demonstrable benefit)"
- Example of my patient suffering quadriplegia after a fall

QUESTIONS/DISCUSSION



OLD PROBLEMS + NEWTECHNOLOGY = BIG IDEAS!

TENNESSEE STATE WORKER'S COMPENSATION CONFERENCE

JUNE 7, 2018

DAVID K. TUTOR, MD

PRESIDENT/MEDICAL DIRECTOR

TAP TO TREAT OCCUPATIONAL TELEMEDICINE

Telemedicine from a Provider's perspective

As a Provider, my greatest benefit is what I can offer to my Industrial Partners and their employees

- 24/7/365 Virtual Clinic on their site complete with RNs, APNs and MDs
- Immediate availability when an injury occurs
- Offered for a fraction of the cost of a conventional onsite clinic



TELEMEDICINE

How to be there – anytime, anywhere for injured workers and employers with provider access 24/7

What's needed:

- Device
- Internet connection
- Private area

What you get:

 Virtual, video/audio, face to face, HIPPA compliant healthcare visit

THE NURSE WILL SEE YOU NOW...

The RN meets the patient in the virtual waiting room, performs triage and directs the treatment path forward per appropriate protocol:

- No treatment
- Simple conservative first aid treatment and follow up with the RN
- Referral to a virtual Tap To Treat advanced practitioner and/or MD for treatment and follow up
- Referral to a brick and mortar medical clinic
- Referral to the Emergency Department



As a Telemedicine Provider

Our purpose is to provide VIRTUAL MANAGEMENT of work related conditions from injury to MMI

- As the ATP or in a case management role
- Two criteria must be met for the ATP to be virtual:
 - 1. The medical condition must be appropriate for virtual management
 - 2. Virtual management must meet the expectations of the injured employee

Our goal is to achieve an excellent outcome for the injured employee while meeting the employer's expectations



What happens in the Emergency Department...

- ED's are necessary, but...
- Injured employees too often receive "knee jerk" referrals to an ED for conditions that do not require that level of care
- Unnecessary ED visits carry a high cost burden for Worker's Compensation
- 24/7 Telemedicine virtual onsite clinics can effectively eliminate the inappropriate ED referrals

By eliminating the ED visit, Telemedicine can help the employee and employer:

- Save the ED charge
- Avoid "obligatory" prescriptions
- Avoid "obligatory" restricted days and lost time
- Avoid potential for unnecessary testing and referrals
- Avoid transportation issues
- Avoid the inconvenience and lost productivity of waiting
- Avoid exposures to infectious illness and other ED "situations"
- Avoid communication gaps



What about the Walk In Clinic?

- Most rural areas do not have occupational health clinics
- Injured employees are commonly referred to Family Docs and Walk In Clinics in these areas
- WC patients receive "primary care/urgent care" treatment when in fact they
 need to be treated differently—more aggressively—to achieve desired
 outcome
- Result—higher cost, more medications, more restricted days and lost time plus higher OSHA recordability risk



An Occupational Telemedicine Provider can

- Provide consistent, Worker's Compensation appropriate injury care and management
- Enable injured workers and employers to avoid the risks associated with unnecessary ED and Walk In Clinic visits



Occupational Telemedicine benefits for the injured worker

- Early intervention with immediate evaluation/treatment for their injury
- Convenience—first visit "onsite", follow up "wherever they're comfortable"
- Avoid travel, wait times and "the flu"
- One point of contact—RN is with them from injury to MMI
- Daily healthcare visits in the acute injury phase
- Avoid unnecessary testing, meds and referrals
- Financial--avoiding lost time + remaining engaged, satisfied and productive

Occupational Telemedicine benefits for the employer

- Cost Savings—reduced ED visits, meds, referrals and lost time
- Reduced restricted days and lost time
- Reduced OSHA recordability risk
- Single point of contact from injury to MMI
- Consistency of process and care across multiple sites
- Injured employee remains engaged and productive at work
- Convenience/saves time
- WC injury management protocols customizable to site specific needs
- Communication capability through multiple platforms

Conclusion

- Telemedicine can play a vital role in the evaluation, treatment and case management of injured workers, either stand alone or in conjunction with conventional providers
- Telemedicine can provide an immediate, convenient alternative to brick and mortar clinics and emergency departments
- Telemedicine provides cost savings, improves communication, reduces restricted days, lost time and OSHA recordability risk while providing consistency of process and care across multiple sites



THANKYOU!

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E-Billing

Abbie Hudgens, Administrator Jay Blaisdell, Coordinator

E-Billing Mandate: TCA 50-6-202

By July 1, 2018:

Providers must:

- 1. Submit TN WC medical bills electronically (837 transaction).
- 2. Receive explanation of benefits electronically via Electronic Remittance Advice (ERA, 835 transaction).
- 3. Receive payment via electronic funds transfer (EFT).

Payers must:

- 1. Receive TN WC medical bills electronically (837 transaction)
- 2. Submit explanation of benefits via ERA (835 transaction)
- 3. Pay bills via electronic funds transfer (EFT)

E-Billing Rules Effective March 13, 2018.



Exemptions

Providers automatically exempt if:

- Less than 10 employees.
- ✓ Les than 120 bill in TN/year.

Payers automatically exempt if:

✓ Less than 250 paid claims in TN/year.

Payers and providers may also be exempted if:

- ✓ They demonstrate to the Administrator that compliance will result in an "Unreasonable Financial burden."
- ✓ Requires submitting a letter and supporting documentation to <u>WC.eBill@tn.gov</u>.



Benefits of E-Billing

Providers:

- Reduces manual work in WC.
- ✓ Minimizes rejections.
- Reduces bill submission costs.
- ✓ Quicker payment.
- Easier auditing and payment accuracy.
- ✓ Reduced duplications.

Payers:

- Reduces administrative costs.
- Improves accuracy.
- EFT and claims identification .



First Steps for Providers

- ✓ Assess capabilities of current electronic records and practice management software
 - 1. Paper or electronic?
 - 2. Ability to generate electronic bill (a.k.a. ANSI-12x 837 file)?
 - 3. Ability electronically export selected medical files without having to manually extract the file?
 - 4. Ability to attach select medical records to respective electronic bill and submit to carrier as one file?
 - 5. Establish a communications interfaces with individual insurance carriers.
 - Contact Workers' Compensation Clearinghouse.



First Steps for Payers

- ✓ Assess capabilities of current electronic records and practice management software
 - 1. Paper or electronic?
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Workers Compensation Clearinghouses









- ✓ Ability to electronically attach records.
- ✓ Interface with payer's clearinghouse.
- ✓ Identify proper claim demographics.



Bureau Position

- Implementation date remains July 1, 2018.
- System interest to continue to develop this process.
- Flexibility.
- Provide information.
- Help identify friction points.
- Be a resource.



Other Resources

Bureau E-Billing Website: https://www.tn.gov/content/tn/workforce/injuries-at-work/available-resources/redirecr-available-resources/medical-e-billing-requirements.html

Bureau Companion Guide: https://www.tn.gov/content/dam/tn/workforce/documents/injuries/TNCompanionGuideforeBilling1418.pdf

How to be Successful: https://coa.org/docs/WhitePapers/WCBillingWhitePaper.pdf

E-Billing Program Rules: http://publications.tnsosfiles.com/rules/0800/0800-02/0800-02-26.20180313.pdf

Jay Blaisdell: jay.blaisdell@tn.gov

IAIABC: https://www.iaiabc.org/iaiabc/default.asp





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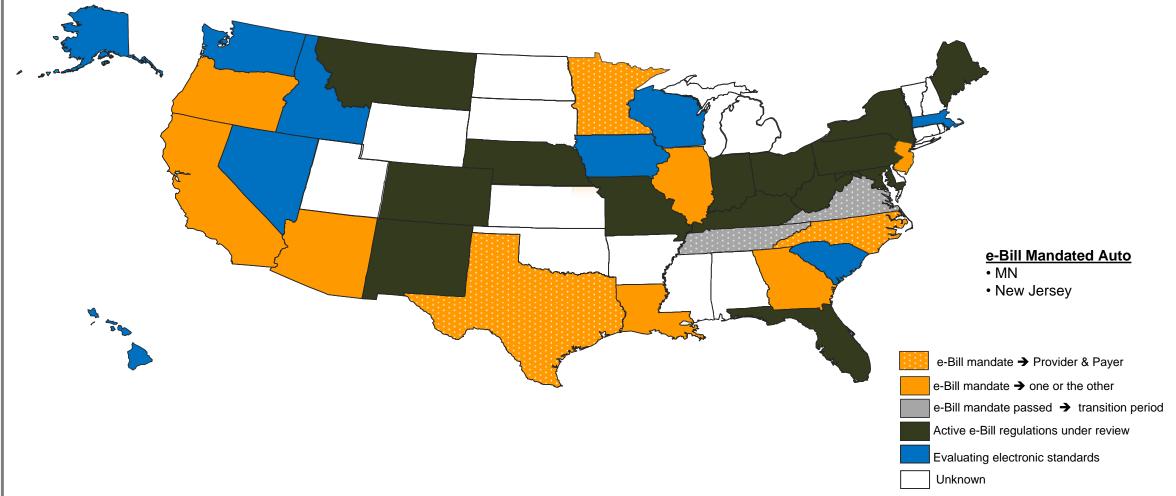




EDI Mandate Market Conditions (Workers' Compensation)

State Compliance Mandates on the Rise

Along with other initiatives across the healthcare industry, several states have begun to mandate that all claims be processed electronically vs. paper, including these types of billings, with several more on the horizon.



Source IAIABC – Int'l Association of Industrial Accident Boards & Commissions (<u>www.iaiabc.org</u>)

Evaluation of claims for FROI and/or SROI (FROI = First Report of Injury, SROI = Subsequent Report of Injury)

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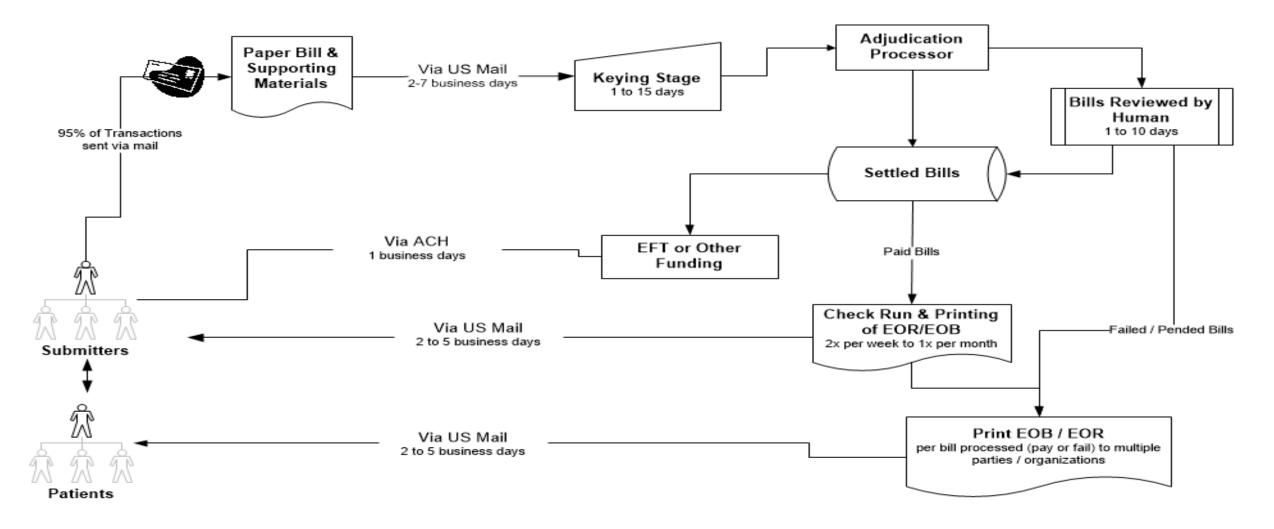
Paper vs EDI Costs

New York ♦ Chicago



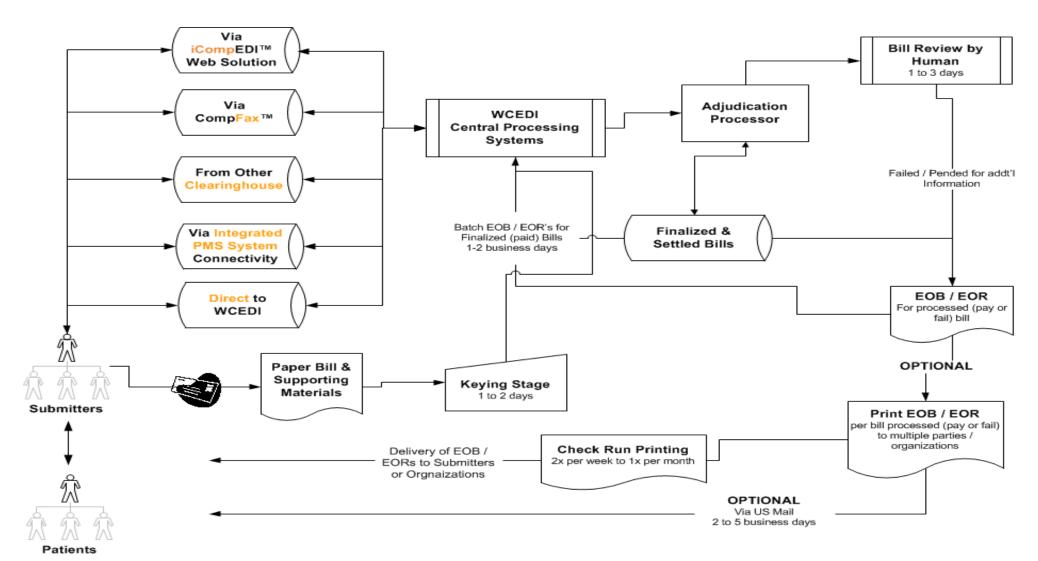
Average Cost: \$0.85 - \$1.50/bill

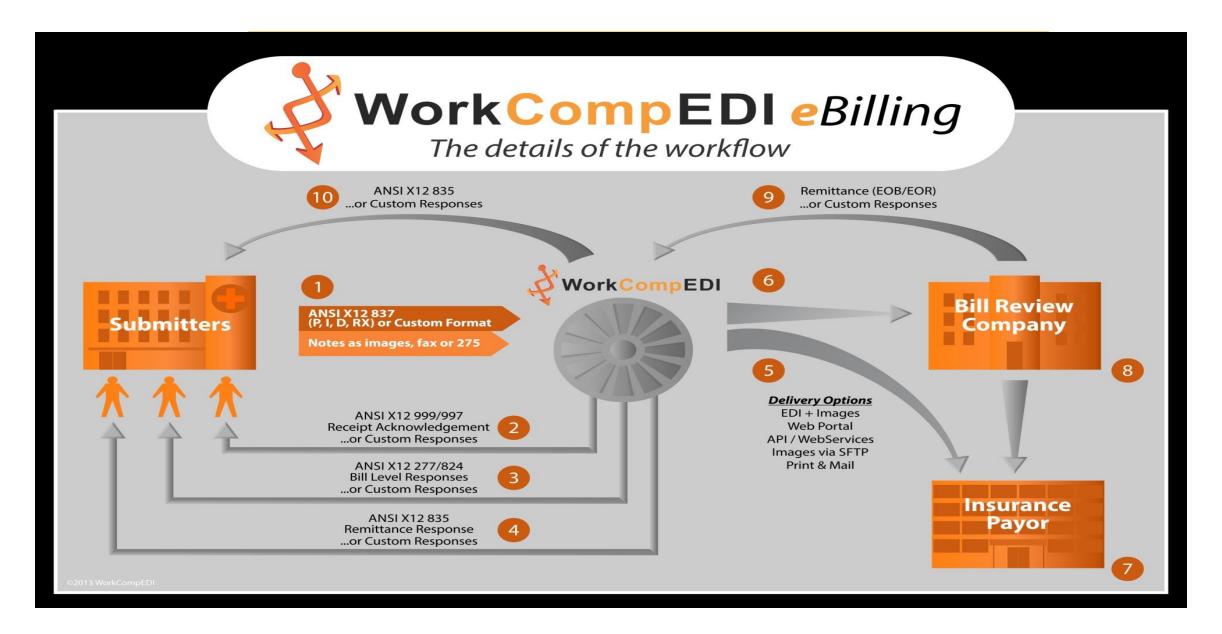
10-30 Day Notices Turn Around





Average Cost: \$0.65 / bill 24hr Delivery Fast Rejection / Payment Notice







Transaction Workflow Explained

Bill file generated

• 837, print image, proprietary, etc.

Attachments indexed

PWK, scan/fax with cover sheet/bard code, etc.

Receiving party generates acknowledgement response

• 997/999/Ack

Receiving party generates bill level notifications/rejections & final remittance

• 277/824/835

If using clearinghouse, bill level notifications will come from clearinghouse first, then Payor or Bill Review company

837 PWK 999 277 835

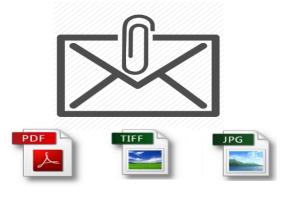
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Attachment Handling Process

Transmission Methods

sFTP (File Transfer) HTTPS (web upload) API



Formats Accepted

275 X12 Format (5010 & 6020)
PDF
TIFF / JPEG / GIF
Other Image Formats

Claims Attachments

- Investment in scanning, document management systems and workflow by payers limits ROI. Provider ROI much higher.
- Lack of consensus on a standard.

 No safe bet for investments.
- Payers want and all provider solution, Providers want an all payer solution.
 - Lack of automation and integration into existing payer attachments processing (still no "automated decision making" for payer).
- Lack of workflow integration with provider billing and EMR systems.

- ✓ Submitting attachments before bills or after, as single images or in bulk, independent of a bill (directly from an EMR/document management system) or indexed by a practice billing system.
- ✓ Able to match bills to images submitted using numerous indexing protocols, which provides an easy way to search and share supporting documents.
- If providers are required to submit specific attachments for a bill, our tools give submitters the ability to classify the type of attachments they are submitting, further helping ensure a "clean submission".
- ✓ COMING SOON: Orphan attachment submission processes



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